

(VI) GROUND OF REJECTION TO BE REVIEWED ON APPEAL

- (1) Claims 19, 20, 22, 23, 27 and 34-42 were rejected under 35 U.S.C. § 102(a) over Amarasinghe et al. (WO 02/45784 A1).
- (2) Claim 21 was rejected under 35 U.S.C. § 103(a) over Amarasinghe et al. in view of Gradon et al. (U.S. 2003/0089373 A1).
- (3) Claims 25, 26 and 28 were rejected under 35 U.S.C. § 103(a) over Amarasinghe et al. in view of Hellings et al. (U.S. 5,975,079).

(VII) ARGUMENT

(1) Claims 19, 20, 22, 23, 27 and 34-42 are Not Anticipated by Amarasinghe et al.

(A) Claim 19 is Not Anticipated by Amarasinghe et al.

The standard of anticipation under 35 U.S.C. §102 is identity of invention. In other words, as stated in M.P.E.P. §2131, “the identical invention must be shown in as complete detail as is contained in the...claim.” (Citing Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)).

Anticipation is a question of fact. See, for example, In re Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). The standard of review applied to findings of fact is the “substantial evidence” standard under the Administrative Procedure Act (APA). See In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). Substantial evidence means “more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” Richardson v. Perales, 402 U.S. 389, 40 (1971).

Amarasinghe et al. do not anticipate claim 19 because Amarasinghe et al. do not disclose or suggest, at least, at least one selected frame portion engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body of the frame.

The November 24, 2008 Office Action states on page 2, paragraph number 3, that the brace 12 of Amarasinghe et al., which the Examiner alleges corresponds to the at least one selected frame portion of claim 19, “is engaged with the cushion 16 (by wrapping around the cushion as seen in Fig. 2) so that the cushion is adjustable (on and off of patient via straps connecting 12) in accordance with a position of said at least one selected frame portion relative to the main body (12).”

Firstly, it is respectfully noted that Amarasinghe et al. do not disclose or suggest that the brace 12 engages the cushion 16. Amarasinghe et al. disclose on page 6, lines 1-15, that the brace 12 assumes a fixed predetermined position with respect to the mask shell 13, the existing mask shell headgear attachment points 17 serving as retaining formations for the brace 12. The brace 12 assumes a substantially constant position relative to the mask shell when the mask assembly is properly located on the user.

The brace 12 of Amarasinghe et al. is not “wrapped around” the cushion 16, as alleged by the Examiner. In fact, the brace head strap attachment points 15 of the brace 12 extend away from, and do not engage, the cushion 16 as shown, for example, in Figs. 3-5 of Amarasinghe et al. It is respectfully submitted that Fig. 2 is not substantial evidence that the brace 12 of Amarasinghe et al. engages the cushion 16 so that the cushion 16 is adjustable in accordance with a position of the brace 12 relative to the mask shell 13.

Secondly, even assuming that the brace head strap attachment points 15 of the brace 12 did engage the mask cushion 16, which Appellants do not concede, such engagement would not adjust the cushion in accordance with a position of the brace 12 relative to the mask shell 13. As disclosed on page 6, lines 6-7, of Amarasinghe et al., the brace 12 assumes a fixed position with respect to the mask shell 13. Accordingly, the cushion of Amarasinghe et al. cannot be adjusted in accordance with a position of the brace 12 relative to the mask shell 13 as the position of the brace 12 is fixed relative to the mask shell 13.

In response to the arguments filed August 14, 2008, the Examiner on page 8, paragraph number 8, of the November 24, 2008 Office Action, states that “a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.”

The Examiner then goes on from pages 8 through 9 of the Office Action and states in the instant case, “the brace (12) is a malleable wire that is engaged with a cushion (via strap and a shell) and the brace is easily maneuvered by hand and Amarasinghe specifically shows portions (15) of brace (12) wrapping around the cushion (16) in Fig. 2. Therefore, the brace (12) is structured to engage the cushion (16) via shell (13) and tightening of the straps; and the tightness of the cushion would inherently be adjusted via the straps connected to brace (12).”

Claim 19 does not recite an intended use of the at least one selected frame portion, nor does claim 19 recite that the at least one selected frame portion is structured to engage with the cushion, as alleged by the Examiner. Claim 19 recites that the at least one selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of said at least one selected frame portion relative to the main body.

Claim 19 also does not recite that the at least one selected frame portion is engaged with the cushion via, for example, a strap or a shell, of the mask assembly. Claim 19, again, recites that the at least one selected frame portion is engaged with the cushion, and not the other features identified by the Examiner. The Examiner concedes the failure of Amarasinghe et al. to disclose or suggest this feature by improperly interpreting claim 19 to recite an intended use and/or improperly interpreting claim 19 to recite that the at least one selected frame portion is structured to engage the cushion, or engages the cushion “via” other elements of the mask assembly. Claim 19 does not recite either. Claim 19 recites that the selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of said at least one selected frame portion relative to the main body.

As also discussed above, Fig. 2 of Amarasinghe et al. does not disclose that the brace “wraps around” the cushion 16, nor does Fig. 2 show the brace 12 engaged with the cushion 16. In fact, as discussed above the remaining Figs. 3-5 of Amarasinghe et al. clearly show that the

brace 12, and the brace headgear strap attachment points 15 of the brace 12, do not contact the cushion 16.

In response to Applicants' arguments filed February 24, 2009, and the arguments presented during the personal interview conducted March 16, 2009, the Examiner, in the continuation sheet provided with the March 27, 2009 Advisory Action, disagrees with Appellants' arguments and states that the selected frame portion (i.e. the brace 12) of Amarasinghe et al. is engaged with the cushion 16 via the main body (i.e. the mask shell 13) and by wrapping around the cushion as seen in Fig. 2 of Amarasinghe et al. The Examiner also states that, moreover, Amarasinghe et al. disclose on page 8, lines 8-16, that "it is also intended that the brace could be configured so as to engage brace receiving features that may be provided by a mask cushion clip. In this way the brace may be accurately positioned relative to the mask frame while serving to secure the cushion clip and cushion to the mask frame." The Examiner concludes that it is thus clear that Amarasinghe et al. disclose at least one selected frame portion (i.e. the brace 12) is engaged with the cushion 16 via the main body (i.e. the mask shell 13) or a cushion clip.

It is respectfully noted that as discussed in the February 24, 2009 response, and during the March 16, 2009 interview, claim 19 does not recite that the at least one selected frame portion is engaged with the cushion via, for example, straps, the mask shell, or a cushion clip, as alleged by the Examiner. Claim 19 recites that the at least one selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body. As discussed above, the brace 12 of Amarasinghe et al. is provided in a fixed predetermined position with respect to the mask shell 13, as disclosed on page 6, lines 6-7, of Amarasinghe et al. Accordingly, the cushion 16 of Amarasinghe et al. is not adjustable in accordance with a position of the brace 12 relative to the

mask shell 13 because the brace 12 is not adjustable relative to the main body. Claim 19 clearly recites that the at least one selected frame portion is adjustable relative to the main body. Amarasinghe et al. do not disclose or suggest this feature, nor does the Examiner provide any substantial evidence support that Amarasinghe et al. disclose this feature.

With respect to the recitation in claim 19 that the at least one selected frame portion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body, the Examiner in the third full paragraph of the continuation sheet of the Advisory Action, states that the cushion of Amarasinghe et al. is adjustable (capable of being adjusted) in accordance with a position of the at least one selected frame portion relative to the main body of the frame because “it is the examiner’s position that the cushion (which is attached to and forms the shape of a user’s face in Fig. 12) is adjustable (capable of being adjusted) by taking the straps on and off the patient; particularly given the malleability of the brace and the brace being detachably connected to the mask.”

It is respectfully noted that claim 19 does not recite that the cushion is adjustable in accordance with the straps of a headgear being placed on or taken off of the patient. Accordingly, even assuming the Examiner’s position that the cushion is adjustable by taking the straps on and off of the patient is correct, which Appellants do not concede, such a position is irrelevant to the determination whether a *prima facie* case of anticipation has been established. In order to establish a *prima facie* case of anticipation, the prior art reference must disclose the identical invention recited in claim 19, including a frame including a main body having at least one selected frame portion engaged with a cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body. It is respectfully submitted that the Examiner’s interpretation of Amarasinghe et al. as including a

cushion that is adjustable by taking the straps on and off of a patient clearly indicates that Amarasinghe et al. do not disclose the identical invention recited in claim 19.

In response to Appellants' arguments that the brace 12 of Amarasinghe et al. is not engaged with the cushion 16 so that the cushion 16 is adjustable in accordance with a position of the brace 12 relative to the mask shell 13, the Examiner, in the fourth paragraph of the continuation sheet of the Advisory Action, states that since Applicant has not provided any specific definition for the term "engaged" the term engaged has been given its common dictionary meaning of "attached to."

As noted in the attached Evidence Appendix, the Examiner has provided Appellants' with dictionary definitions for the term "engaged." The definition of the term "engaged" provided with the Interview Summary mailed March 23, 2009 (from the Encyclopedia Britannica Online) does not include the definition of "attached to." It is further respectfully noted that none of the dictionary definitions forwarded with the March 27, 2009 Advisory Action include the definition of "engaged" as "attached to."

With respect to the Examiner's conclusion that because "Applicant has not provided any specific definition for the term 'engaged'; the term engaged has been given its common dictionary meaning," it is respectfully noted that Applicants are not required to provide a specific definition for every claim term, and that the broadest reasonable interpretation given to claim terms requires that the PTO apply to the claim terms the broadest reasonable meaning in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the specification. See, for example, M.P.E.P. §2111. As also noted in that M.P.E.P. section, the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.

As also noted in M.P.E.P. §2111.01, the ordinary and customary meaning of a term may be evidenced by a variety of sources, including the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art. (Citing Phillips v. AWH Corp., 415 F.3d 1303, 1314, 75 USPQ 2.d, 1321, 1327 (Fed. Cir. 2005)).

As noted in M.P.E.P. §2111.01, to determine the ordinary and customary meaning of the claim term, the intrinsic evidence must first be considered. In other words, the words of the claims themselves, and the remainder of the specification, including the prosecution history, must first be considered when construing the meaning of a claim term. Only if a review of the intrinsic evidence fails to provide an ordinary and customary meaning of the claim term is resort to intrinsic evidence, such as dictionary definitions as relied upon by the Examiner, permitted. In the instant application, it is respectfully submitted that it is clear from the words of the claims themselves, and from the remainder of the specification and the prosecution history, that Applicants' recitation in claim 19 of the at least one selected frame portion being engaged with the cushion so that the cushion is adjustable in accordance with the at least one selected frame portion relative to the main body does not mean that the at least one selected frame portion is "attached to" the cushion.

It is further respectfully noted that even assuming the Examiner's resort to extrinsic evidence for construction of the term "engaged" is correct, which Appellants do not concede, such a construction still fails to establish a *prima facie* case of anticipation as the brace 12 of Amarasinghe et al. is not "attached to" the cushion 16. The brace 12 is clearly connected to the mask shell 13.

As Amarasinghe et al. do not disclose the identical invention recited in claim 19, the rejection fails to present a *prima facie* case of anticipation. As the Examiner has not provided

any substantial evidence that the brace 12 of Amarasinghe et al. engages (e.g. "wraps around") the cushion 16 so that the cushion 16 is adjustable in accordance with a position of the brace 12 relative to the mask shell 13, the rejection is improper and must be reversed.

(B) Claim 20 is Not Anticipated by Amarasinghe et al.

Claim 20 recites that at least one headgear connector portion is provided to the at least one selected frame portion and the at least one selected frame portion is adapted to be movable in accordance with change in headgear strap tension to thereby adjust the force applied to the size of the patient's nose and/or face in use.

The Examiner, on page 3, lines 9-13, of the Office Action, alleges that the brace head strap attachment points 15 of the brace 12 of Amarasinghe et al. are adapted to be movable in accordance with a change in headgear strap tension and directs Applicants' attention to Fig. 2 of Amarasinghe et al. Appellants respectfully disagree.

As discussed above, Amarasinghe et al. disclose that the brace depicted in Fig. 2 assumes a substantially constant position relative to the mask shell when the mask assembly is properly located on the user. See page 6, lines 9-12, of Amarasinghe et al. In other words, Amarasinghe et al. clearly disclose that no portion of the brace 12, including the brace head strap attachment points 15, is adjusted relative to the mask shell 13 when the mask assembly is located on the user.

In response to Appellants' arguments regarding claim 20, the Examiner in the continuation sheet of the March 27, 2009 Advisory Action, responds that Amarasinghe et al. disclose that "the versatility offered by the [brace 12]... offers the possibility for incorporating a mask stabilizing feature independent of, or in addition to, the inclusion of the headgear attachment points [15]. An example of such a stabilizing feature of Amarasinghe et al. is illustrated in the accompanying drawings in the form of a forehead stabilizing section 20[, as part

of the brace 12]. The stabilizing portion 20 takes the form of a portion of the brace 12 extending clear of the mask shell 13 so as to provide an elevated brace that allows the position of the stabilizing portion 20 to be adjusted for individual patients.” The Examiner further notes that in “Fig. 2 of Amarasinghe et al., it can be seen that the forehead stabilizing portion 20 is in near contact or contact with the user’s forehead, thereby limiting movement of the accompanying mask frame and mask cushion toward the user’s face in the region of the nasal bridge.”

It is respectfully submitted that there is nothing in this disclosure of Amarasinghe et al. noted by the Examiner that discloses or suggests that the brace 12 includes at least one headgear connector portion that is adapted to be movable in accordance with a change in headgear strap tension to thereby adjust the force applied to the patient’s nose and/or face in use.

During the interview, the Examiner stated that the cushion of Amarasinghe et al. is adjustable by loosening or tightening the straps. See the Interview Summary. However, claim 20 recites that the at least one selected frame portion is adapted to be movable in accordance with the change in headgear strap tension. As noted above, the brace 12 is kept in a fixed predetermined position relative to the mask shell 13. See page 6, lines 6-7 and 11-12 of Amarasinghe et al. The brace 12 is clearly not adapted to be movable in use.

(C) Claim 22 is Not Anticipated by Amarasinghe et al.

As discussed above, Amarasinghe et al. do not disclose or suggest that the brace head strap attachment points 15 either “wrap around” the cushion 16 or engage the cushion 16. Furthermore, as also discussed above, Amarasinghe et al. disclose that the brace 12 assumes a substantially constant position relative to the mask shell. In other words, Amarasinghe et al. do not disclose or suggest that the brace head strap attachment points 15 wrap around the cushion when the straps are fitted around a user’s head, as alleged by the Examiner.

With respect to Appellants' arguments regarding claim 22, the Examiner in the March 27, 2009 Advisory Action alleges that the headgear attachment points 15 of the brace 12 of Amarasinghe et al. "wrap around" the cushion as shown in Fig. 2. As discussed during the interview, it is respectfully submitted that Fig. 2 of Amarasinghe et al. does not show the headgear attachment points 15 "wrapped around" the cushion 16. As clearly shown, for example, in Fig. 4 of Amarasinghe et al., the headgear strap attachment points 15 clearly do not "wrap around" the cushion 16. See also, Fig. 3 of Amarasinghe et al.

(D) Claim 23 is Not Anticipated by Amarasinghe et al.

Claim 23 recites that the main body and the at least one selected frame portion are provided as two separate parts that are coupled to one another. As discussed above, the brace 12 of Amarasinghe et al. does not correspond to the at least one selected frame portion of claim 23 and base claim 19 because the brace 12 of Amarasinghe et al. does not engage the cushion 16, as recited in base claim 19.

In response to Appellants' arguments regarding claim 23, the Examiner in the March 27, 2009 Advisory Action states that "claim 19 merely recites that 'at least one selected frame portion is engaged with the cushion.'" It is respectfully noted, however, that claim 23 does not "merely recite" that the at least one selected frame portion is engaged with the cushion. Claim 23, which depends from base claim 19, recites that the at least one selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body. As also noted above, base claim 19 recites that the at least one selected frame portion is adjustable relative to the main body. As further noted above, the brace 12 of Amarasinghe et al. assumes a fixed predetermined position on the mask shell 13 and is not adjustable relative to the mask shell 13.

(E) Claim 24 is Not Anticipated by Amarasinghe et al.

Claim 24 recites that the main body and the at least one selected frame portion are movable by a camming mechanism.

The Examiner states on page 4, lines 1-9, of the Office Action, that “there is no structural limitation added to this claim.” The Examiner then goes on to state that it is his “position that the main body and the selected portion” of Amarasinghe et al. (i.e. the shell 13 and the brace 12) “are movable by a camming mechanism...[s]ince a cam is merely a projecting part of a rotating wheel or shaft that strikes a lever at one or more points on its circular path, if a cam were to contact a mask, or a package containing the mask, the main body and the selected portion would be movable by a camming mechanism.” The Examiner then concludes that “[s]ince the camming mechanism is not part of the claimed apparatus, and the main body and the at least one selected frame portion” (i.e. the shell 13 and the brace 12) “are deemed to be movable by a camming mechanism, the apparatus disclosed by Amarasinghe et al. meets the claim.”

The Examiner’s determination that a camming mechanism is not part of the mask assembly of claim 14 is simply incorrect. Claim 24 plainly and clearly recites that the main body and the at least one selected frame portion are movable by a camming mechanism. It is also unclear how the Examiner can conclude that claim 24 does not require the prior art to disclose or suggest a camming mechanism, but then conclude that Amarasinghe et al. do disclose a camming mechanism and thus “meet the claim.”

Applicants also respectfully note that the Examiner does not cite any portion of Amarasinghe et al. allegedly corresponding to a camming mechanism, as required by 37 C.F.R. §1.104(c)(2). Furthermore, the Examiner’s determination that “if a cam were to contact the mask, or a package containing the mask, the main body and the selected portion would be movable by a camming mechanism,” is nothing more than speculation on the part of the

Examiner. If Amarasinghe et al. actually disclosed the features recited in claim 24, Amarasinghe et al. would anticipate the claimed invention. However, as Amarasinghe et al. do not disclose or suggest the invention recited in claim 24, Amarasinghe et al. do not anticipate the claim.

In response to Appellants' arguments, the Examiner responds in the March 27, 2009 Advisory Action that "claim 24 is drawn to an apparatus, the apparatus is not claimed as having a cam, or a camming mechanism, as claim 24 only requires the main body and the at least one selected frame portion being capable of being moved by a camming mechanism."

It is apparently the position of the Examiner that there are some "magic words" that are required in order to claim that the mask assembly includes a camming mechanism. As has been noted throughout the prosecution of this application, both by the Examiner and the Appellants, the proper examination of the application requires that the claims be given their broadest reasonable interpretation as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in the specification, and the broadest reasonable interpretation must also be consistent with the interpretation that those skilled in the art would reach. As also noted by Appellants during the prosecution of this application, the establishment of a *prima facie* case of anticipation requires that the prior art reference disclose the identical invention in as much detail as is recited in the claim.

It is respectfully submitted that the Examiner's semantic exercise in alleging that "since a cam is merely a projecting part of a rotating wheel or shaft...if a cam were to contact a mask, or a package containing the mask, the main body in a selected portion would be movable by a camming mechanism" is neither the broadest reasonable interpretation of the claim nor an explanation of how Amarasinghe et al. disclose the identical invention recited in claim 24 in as much detail as is recited in the claim.

(F) Claim 27 is Not Anticipated by Amarasinghe et al.

Claim 27 recites that the at least one selected frame portion includes each lateral side of the frame which is made of a flexible material.

The Office Action on page 4, lines 10-12, alleges that Amarasinghe et al. disclose that the brace head strap attachment points 15 are made of a flexible material and directs Applicants' attention to page 7, lines 21-27, of Amarasinghe et al.

Amarasinghe et al. disclose that the brace 12 is constructed of mild steel wire butt-welded so as to assume a continuous form. The wire is bent to the appropriate configuration using standard wire bending techniques which may include automated bending by way of a suitably programmed wire bending machine.

It is respectfully submitted that Amarasinghe et al.'s disclosure of a brace 12 formed of bent steel wire is not a disclosure of at least one selected frame portion including each lateral side of a frame being made of a flexible material, as recited in claim 27. In fact, Amarasinghe et al. disclose on page 7, lines 18-20, that the brace 12 is relatively rigidly engaged with the mask shell 13.

In response to Appellants' arguments regarding claim 27, the Examiner provides a dictionary definition of flexible as being able to bend without breaking. Even assuming, however, that the Examiner's interpretation that the malleable brace 12 of Amarasinghe et al. corresponds to the flexible material of the selected frame portion of claim 27, which Appellants do not concede, such an interpretation would still not establish a *prima facie* case of anticipation. It is respectfully noted that the dictionary definition of "flexible" provided by the Examiner includes the definitions: 1) able to bend without breaking; 2) not stiff or bent; or 3) pliant.

As noted above, claim 19, from which claim 27 depends, states that the at least one selected frame portion engages the cushion so that the cushion is adjustable in accordance with a

position of the at least one selected frame portion relative to the main body. Claim 27 recites that the at least one selected frame portion includes each lateral side of the frame is made of a flexible material. Amarasinghe et al., on the other hand disclose, for example, on page 7, lines 18-20, that the brace 12 is relatively rigidly engaged with the mask shell 13. It is respectfully submitted that interpreting the brace 12 of Amarasinghe et al. and its rigid engagement with the mask shell 13 is neither a fair interpretation of the disclosure of Amarasinghe et al., nor is it a disclosure of the identical invention recited in claim 27 when the claim is given its broadest reasonable interpretation consistent with the interpretation that those skilled in the art would reach.

(G) Claim 34 is Not Anticipated by Amarasinghe et al.

Claim 34 recites a mask assembly for application of non-invasive positive pressure ventilation to a patient comprising, *inter alia*, a selected frame portion engaged with a cushion so that the cushion is adjustable in accordance with a position of the selected frame portion relative to a main body of the frame. Claim 34 further recites that the selected frame portion includes each lateral side of the frame and a selected frame portion as bendable to cause each lateral side of the frame to push against sides of the cushion.

As discussed above with respect to independent claim 19, Amarasinghe et al. do not disclose or suggest that the brace 12 engages the cushion 16. Furthermore, Amarasinghe et al. do not disclose or suggest that the brace 12 is bendable to cause lateral sides of the shell 13 to push against sides of the cushion 16. Accordingly, Amarasinghe et al. do not anticipate claim 34.

In response to Applicants' arguments that Amarasinghe et al. do not disclose a selected frame portion being bendable to cause each lateral side of the frame to push against the sides of the cushion, the Examiner responds on page 9, lines 13-15, of the Office Action, that

Amarasinghe et al. disclose that the brace 12 is bendable and the brace 12 surrounds the body of the mask with lateral projections (i.e. the brace head strap attachment points 15) of the brace 12.

As discussed above, Amarasinghe et al. do not disclose that the brace 12 either wraps around the cushion 16 or engages the cushion 16. Furthermore, Amarasinghe et al. do not disclose or suggest that the brace 12 is bendable to cause lateral sides of the mask shell 13 to push against sides of the cushion 16. Amarasinghe et al. clearly disclose on page 6, lines 6-7, that the brace 12 assumes a fixed predetermined position with respect to the mask shell 13.

In response to Appellants' arguments regarding claim 34, the Examiner in the March 27, 2009 Advisory Action states that "Amarasinghe clearly teaches side projecting members (15) that the capable of being bent to cause each lateral side of the frame to push against sides of the cushion. See: Figs. 2-4."

It is respectfully submitted that Amarasinghe et al. do not disclose or suggest, even remotely, that the brace head strap attachment points 15 are capable of being bent to cause each lateral side of the mask shell 13 to push against sides of the cushion 16. Amarasinghe et al. do not even disclose or suggest that the brace head strap attachment points 15 are capable of being bent to cause the attachment points 15 to push against the sides of the cushion 16. There is nothing in the disclosure of Amarasinghe et al. that discloses or suggests that the brace 12 engages the cushion 16 so that the cushion 16 is adjustable in accordance with a position of any portion of the brace 12 with respect to the mask shell 13. The Examiner has simply concluded, incorrectly, that the brace 12 "wraps around" the cushion 16 from the perspective view of Fig. 2. This interpretation of Fig. 2 of Amarasinghe et al. is not supported by any portion of the text of Amarasinghe et al., and it plainly inconsistent with the views shown in Figs. 3-5 of the reference. As such, Fig. 2 can hardly serve as substantial evidence for the conclusion that Amarasinghe et al. disclose the identical invention recited in claim 34 in as much detail as is recited.

(H) Claim 35 is Not Anticipated by Amarasinghe et al.

With respect to claim 35, the Examiner alleges on page 5, lines 4-6, of the Office Action, that the stabilizing portion 20 of Amarasinghe et al. supports the cushion 16. The Examiner directs Appellants' attention to page 7, lines 8-20, of Amarasinghe et al. It is respectfully noted, however, that Amarasinghe et al. do not disclose or suggest anything about the stabilizing portion 20 of the brace 12 supporting the cushion 16, as alleged by the Examiner. Page 7, lines 8-20, of Amarasinghe et al. does not provide substantial evidence that Amarasinghe et al. disclose the identical invention recited in claim 35.

(I) Claim 36 is Not Anticipated by Amarasinghe et al.

With respect to claim 36, as Amarasinghe et al. do not disclose or suggest a flexible member supporting the cushion, Amarasinghe et al. cannot anticipate or render obvious the claim.

(J) Claim 37 is Not Anticipated by Amarasinghe et al.

With respect to claim 37, as the shell 13 and the brace 12 of Amarasinghe et al. do not correspond to the main body and the selected frame portion, the claim is neither anticipated nor rendered obvious by the reference.

(K) Claim 38 is Not Anticipated by Amarasinghe et al.

Claim 38 recites that the selected frame portion includes each lateral side of the frame which is made of a flexible material. As discussed above with respect to, for example, claim 27, the wire brace 12 of Amarasinghe et al. is not made of a flexible material. As also discussed above, the brace head strap attachment points 15 of Amarasinghe et al. are not bendable or flexible as Amarasinghe et al. disclose on page 7, lines 18-20, that the brace 12 is relatively rigidly engaged with the mask shell 13 and disclose on page 6, lines 6-7, that the brace 12 assumes a fixed predetermined position with respect to the mask shell 13.

(L) Claim 40 is Not Anticipated by Amarasinghe et al.

With respect to claim 40, the brace head strap attachment points 15 of Amarasinghe et al. do not correspond to the side wing portions as alleged by the Examiner because they are not movable relative to the mask shell 13 to adjust sides of the cushion 16.

(2) Claim 21 is Not Obvious over Amarasinghe et al. in View of Gradon et al.

As noted in MPEP § 2141, the Supreme Court reiterated in KSR International Co. v. Teleflex Inc., 550 U.S. 398, 82 USPQ2d 1385 (2007), that the framework for the objective analysis for determining obviousness under 35 U.S.C. 103 is stated in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966). Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows: (A) Ascertaining the differences between the claimed invention and the prior art; and (B) Ascertaining the differences between the claimed invention and the prior art; and (C) Resolving the level of ordinary skill in the pertinent art.

As also noted in MPEP § 2141, Office personnel fulfill the critical role of factfinder when resolving the Graham inquiries. It must be remembered that while the ultimate determination of obviousness is a legal conclusion, the underlying Graham inquiries are factual. When making an obviousness rejection, Office personnel must therefore ensure that the written record includes findings of fact concerning the state of the art and the teachings of the references applied. In certain circumstances, it may also be important to include explicit findings as to how a person of ordinary skill would have understood prior art teachings, or what a person of ordinary skill would have known or could have done. Factual findings made by Office personnel are the necessary underpinnings to establish obviousness. As noted above, the standard of review applied to findings of fact is the “substantial evidence” standard under the APA. Gartside at 1315.

The determination of obviousness requires the resolution of at least three factual inquiries. The Examiner has failed to correctly determine the scope and content of the prior art, namely Amarasinghe et al., with respect to independent claim 19 for the reasons discussed above. The Examiner has not provided substantial evidence support for finding that Amarasinghe et al. disclose or suggest at least one selected frame portion is engaged with the cushion so that the cushion is adjustable in accordance with a position of the at least one selected frame portion relative to the main body. As the Examiner has failed to correctly resolve the scope and contents of the prior art, the Examiner has also failed to correctly resolve the differences between the claims and the prior art.

Obviousness requires a suggestion of all the elements in a claim (CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003)) and “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 418 (2007).

Gradon et al. fail to cure the deficiencies of Amarasinghe et al. noted above with respect to independent claim 19 and even assuming it would have been obvious to combine the reference, which Appellants do not concede, the combination would not include all of the features of claim 19, or claim 21.

Furthermore, there is no reason that would have prompted one of ordinary skill in the art to combine Amarasinghe et al. and Gradon et al. The Examiner states on page 7, lines 1-6, of the November 24, 2008 Office Action that “[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mask assembly disclosed by Amarasinghe by replacing the stabilizing forehead portion of Amarasinghe with the adjustable forehead stabilizing portion as taught by Gradon because of the reasonable

expectation of obtaining a mask assembly that could be adjusted easily and quickly without having to undue [sic] the straps." Appellants respectfully disagree.

Firstly, it is respectfully submitted that the Examiner has failed to correctly determine the scope and contents of Gradon et al. There is nothing in the disclosure of Gradon et al. that suggests that the knob 440 allows easy and quick adjustment of the bridge member 430 without having to undo the straps. In fact, there is nothing in the disclosure of Gradon et al. that suggests that the knob 440 allows any adjustment of the bridge member 430 without having to undo the straps.

Secondly, Amarasinghe et al. disclose on page 9, lines 1-6, that by making the mask brace of malleable material, the user can make some adjustment to the position of the headgear retaining portion (i.e. the attachment points 15) and/or the mask stabilizing feature (i.e. the stabilizing portion 20) for rapid tailoring of the mask assembly to a user's particular requirements. It would be hard to conceive of an easier and/or quicker adjustment of the stabilizing section 20 of Amarasinghe et al. than the malleable brace 12. Certainly, modifying the brace 12 of Amarasinghe et al. to have a knob 440 such as disclosed by Gradon et al. would make the adjustment more difficult and slower, not easier and quicker. Gradon et al. disclose in paragraph [0053] that the knob 440 must be loosened and tightened in order to effect adjustment of the bridge member 430. In contrast, the stabilizing section 20 of Amarasinghe et al. may be adjusted simply by bending it by hand. No loosening and then retightening required. One of ordinary skill in the art would not have been prompted to combine Amarasinghe et al. and Gradon et al.

(3) Claims 25, 26 and 28 are Not Obvious over Amarasinghe et al. in view of Hellings et al.

(A) Claims 25 and 26 are Not Obvious over Amarasinghe et al. in view of Hellings et al.

Hellings et al. fail to cure the deficiencies of Amarasinghe et al. with respect to independent claim 19 and even assuming it would have been obvious to combine the references, which Appellants do not concede, the combination would not include all of the features of claim 25 or claim 26 and would not present a *prima facie* case of obviousness.

(B) Claim 28 is Not Obvious over Amarasinghe et al. in view of Hellings et al.

Claim 28 recites the cushion includes at least one element providing for multiple stiffening rates of the cushion upon changes in the force.

With respect to claim 28, page 8, lines 1-5, of the November 24, 2008 Office Action states “the stiffening rate of the cushion taught by Hellings is directly attributable to the rate the gas is supplied to the mask. Thus, by adjusting the gas delivery rate, the cushion stiffening rate would also be adjusted. Thus, the combined references teach a cushion with at least one element providing for multiple stiffening rates as claimed.”

It respectfully noted that claim 28 recites that the at least one element provides for multiple stiffening rates of the cushion upon changes in the force applied to the patient, not upon the rate gas is supplied to the mask. It is also respectfully noted that Hellings et al. provide a separate air pump (not illustrated, see column 3, line 10) attached to the nipple 12 for inflation of the soft pliable material 7, and do not disclose that the stiffening rate of the soft pliable material 7 is adjustable based on the gas supplied to the mask 1, i.e. the gas supplied for patient breathing. Thus, even assuming it would have been obvious to combine Amarasinghe et al. and Hellings et al., which Appellants do not concede, such a combination would not result in the invention of claim 28.